

Attorney Docket: 037003-0275581

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of:  
Anderson *et al.*

Confirmation Number: 2393

Application No.: 09/576,124

Group Art Unit: 1642

Filed: May 22, 2000

Examiner: Phillip Garabel

Title: Treatment of Crohn's Disease Using Anti-CD80 Antibodies That Do Not Inhibit the Binding of CD80 Antigen to CTLA-4

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Mitchell Reff, Ph.D., do hereby declare and state as follows:

1. I am presently at Biogen IDEC and a co-inventor of the present application. I have been employed by Idex Pharmaceuticals Corporation, now Biogen Idec Inc., since May 21, 1990 I was actively working on the subject matter of the present invention prior to and upon filing of the application in the USPTO. Based on the foregoing, I am in a position to attest to the following facts.

2. The following sequence errors were noted in the original nucleotide and amino acid sequence for the 16C10 light chain antibody in an Amendment Filed Concurrently with a Request for Continued Examination Pursuant to 37 C.F.R. §1.114 and Petition Pursuant to 37 C.F.R. §1.313(c)(2) filed on July 26, 2005 with a supplement filed August 9, 2005. Nucleotide position 63 of SEQ ID NO: 9 as originally filed disclosed a thymine (t), while the corresponding amino acid sequence at this position disclosed a valine (Val). Nucleotide position 412 of SEQ ID NO: 9 disclosed a thymine (t), while the corresponding amino acid sequence was a serine (Ser). In SEQ ID NO: 10, the amino acid sequence at position 23 was disclosed as a valine (Val), while the amino acid at position 138 was a serine (Ser).

30551972v1

3. The substitute sequence listing filed July 26, 2005 amended SEQ ID NOS: 9 and 10. Specifically, the thymine at position 68 of SEQ ID NO: 9 was corrected to a cysteine (c), thus changing the corresponding amino acid from a valine (Val) (gtc) to an alanine (Ala) (gcc). The thymine at position 412 of SEQ ID NO: 9 was corrected to an adenine (a) thereby changing the corresponding amino acid from a serine (Ser) to a threonine (Thr). In SEQ ID NO: 10, the amino acid at position 23 was corrected from a valine (Val) to an alanine (Ala), and the amino acid at position 138 was corrected from a serine (Ser) to a threonine (Thr).

4. Figure 5A of the application displays the nucleotide and amino acid sequence for the 16C10 light chain antibody. The following errors in the originally filed Figure 5A were noted in the Amendment Filed Concurrently with a Request for Continued Examination Pursuant to 37 C.F.R. §1.114 and Petitions Pursuant to 37 C.F.R. §1.313(c)(2) filed on July 26, 2005. Nucleotide position 68 of original Figure 5A disclosed a thymine ("t"). Nucleotide position 412 of Figure 5A disclosed a thymine ("t"). Original Figure 5A displayed a valine (V) at amino acid sequence position 23, and a serine (S) at amino acid position 138. These were inadvertent errors.

5. The replacement Figure 5A, filed on July 26, 2005, amended originally filed Figure 5A. Specifically, the thymine at nucleotide position 68 was corrected to a cysteine (c), and the corresponding amino acid at amino acid position 23 was corrected from a valine (V) to an alanine (A). The thymine at position 412 was corrected to an adenine (a), and the amino acid at position 138 was corrected from a serine (S) to a threonine (T).

6. I declare that the amendment to the nucleotide and amino acid sequence of the 16C10 light chain antibody as described in paragraph 2 above, now teach the correct nucleotide and amino acid sequences for the 16C10 light chain antibody specifically identified in the application as originally filed.

7. I further declare that hybridoma HB-12119 of the American Type Culture Collection (ATCC) produces the 16C10 antibody and was received by the ATCC depository May 29, 1996. The nucleotide sequence encoding the 16C10 antibody and produced by hybridoma ATCC accession number HB-12119 corresponds to the corrected nucleotide sequence as set forth in amended SEQ ID NO: 9. The nucleotide sequence set forth in amended SEQ ID NO: 10 encodes the amino acid sequence as set forth in SEQ ID NO: 10. In addition, the 16C10 nucleotide and amino acid sequences expressed by hybridoma ATCC

accession number HB-12119 corresponds to the nucleotide and amino acid sequences in replacement Figure 5A. Accordingly, the substitute nucleotide and amino acid sequence listing (SEQ ID NOS: 9 and 10) for the 16C10 light chain antibody does not constitute new matter because these sequences are the correct sequences for the 16C10 light chain antibody specifically identified in the originally filed application as expressed by hybridoma (HB-12119).

8. I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of the application or any patent issued thereon.

03/01/2006

Date



Mitchell Reff, Ph.D.

30551972v1

3